

PATENT
PC7250AMEB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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IN RE APPLICATION OF: : EXAMINER:

DOUGLAS J. M. ALLEN ET AL. : :

CONTINUATION OF: :

SERIAL NO.: 07/449,961 : ART UNIT:

FILED: DECEMBER 21, 1992 : :

FOR: AZITHROMYCIN DIHYDRATE : :

Hon. Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Commissioner of Patents and Trademarks, Washington, D.C. 20231, on this 28th day of April 1994 By Helen R. Hangac

DECLARATION UNDER 37 C.F.R. § 1.132

I, Helen R. Hangac, declare that:

1. I received a Ph.D. degree in Analytical Chemistry from Duke University in 1982.

2. I have been employed by Pfizer Inc, assignee of the above-identified application, in the Analytical Research and Development Department at Groton, Connecticut since 1982. My current position is that of project leader in which I am responsible for analytical procedures performed on experimental pharmaceuticals, including azithromycin.

3. I am familiar with the subject matter of the above-identified application.

4. A series of experiments were performed under my direction by Near Infrared Spectroscopy and X-ray Powder Diffraction to determine if significant amounts of azithromycin dihydrate (Type A) were present in azithromycin (Type B) a hygroscopic monohydrate. The azithromycin (Type B) lots examined/used in the studies are listed in Table 1. The azithromycin (Type B) lots utilized in the experiments were manufactured using three different crystallizing solvent systems, i.e., ethanol/water, acetone/chloroform, and acetone. All lots of azithromycin (Type B) listed in Table 1 have been shown to be equivalent using infrared spectrometry, and/or X-ray

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diffraction and are equivalent to the original sample described by Bright in U.S. Patent 4,474,768.

| AZITHROMYCIN TYPE B LOTS EXAMINED/USED IN NEAR IR AND X-RAY STUDIES | | |
|--|--------|--------------------|
| LOT NUMBER | TYPE | SOLVENT SYSTEM |
| 1022107 | TYPE B | ACETONE/CHLOROFORM |
| 4351080 | TYPE B | ACETONE/CHLOROFORM |
| 1039117 | TYPE B | ACETONE/CHLOROFORM |
| 4101026 | TYPE B | ETHANOL/WATER |
| 13,577-209-1F | TYPE B | ETHANOL/WATER |
| 4101036 | TYPE B | ACETONE/CHLOROFORM |
| 17,419-216-3 | TYPE B | ACETONE |
| 11,860-18-1 ¹ | TYPE B | ETHANOL/WATER |

¹Sample referenced in Bright, U.S. Patent 4,474,768, Example 3.

5. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

April 19, 1994

Date

Helen H. Hangac

Helen H. Hangac

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